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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,387

01/14/2005

Reiner Luttmann

SARTORIUS-12

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1218 7590 07/24/2009  
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EXAMINER

HOBBS, MICHAEL L

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

07/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/521,387	<b>Applicant(s)</b> LUTTMANN ET AL.	
	<b>Examiner</b> MICHAEL HOBBS	<b>Art Unit</b> 1797	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 17 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 1-19.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

/M. H./  
 Examiner, Art Unit 1797

/William H. Beisner/  
 Primary Examiner, Art Unit 1797

Continuation of 3. NOTE: the proposed amendment raises a new issue in independent claims 1 and 17 with the introduction of the second regulator that monitors the weight of the bioreactor and controls an upstream feed pump. Therefore, to address this new limitation would require more than nominal search and consideration on the part of the Examiner.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues starting on page 8 and continuing through the top of page 10 that the combined references of Cornelissen, Major, Gruenberg and Lucido does not disclose a second regulator connected to weight balance and an upstream feed pump. As this limitation was not part of the previous claim set, the proposed amendment, as stated above, raises new issues that would require more than nominal search and consideration on the part of the Examiner.

Regarding Applicant's argument on page 11 that Lucido is non-analogous art and that the system is not comparable to an automated system for determining cell concentration. In response to applicant's argument that Lucido is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). This is not found persuasive since the system of Cornelissen is an automated system that can determine cell concentration and the teaching that Lucido brings to the applied prior art is the use of an optical sensor in determining cell concentration which, as demonstrated by Lucido, was a known technique at the time of the instant application and solves a similar problem to the instant application.

Regarding the software system and Applicant's assertion of improper hindsight reasoning, the embodiment of Cornelissen for this rejection does not mention receiving signals from a bioreactor for controlling and optimizing a reaction, but the use of an automated system is disclosed within the reference. Furthermore, the applied reference Gruenberg shows within the Figures that sensors are used to monitor the reaction within the bioreactor and are connected to a process control computer by an RS-232 connection. This strongly implies a data signal is sent back to the process computer. Therefore, modification of the control software to adjust the input of nutrients or the removal of culture medium from the bioreactor would naturally flow from the combined teachings of Cornelissen, Major and Gruenberg. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regards to Applicant's argument in reply to the rejections of claims 17-19, that the Examiner did not address the arguments relating to the device claims and that the prior art does not disclose the claimed invention. The Examiner respectfully disagrees with this assertion. The newly added limitation of the second regulator notwithstanding, the combined references monitor the cultivation of cells and, as stated, the sensors and pumps of the applied prior art are fully capable of performing the intended use of monitoring cell concentration and removing excess cells from the bioreactor. Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Therefore, the rejections of the previous claim set are proper and will be maintained.